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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,306

Applicant(s)

GILBERT ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claims 1-34 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification, while being enabling for the treatment of certain human, lung and breast carcinomas, does not reasonably provide enablement for treatment in general as claimed in claim 29. First, the said compound does not treat all ailments (e.g. disease, infections, etc). The use of said compound for treatment in general is not enabled since ailments or diseases or infections does not have a single recognized cause. In fact, the aforementioned ailments or diseases or infections are recognized as having numerous causes and contributing factors, ranging from hereditary considerations, to lifestyles choices such as diets and personal habits. These are only a minute quantity of the factors that promote ailments or diseases or infections, in people. Therefore, the treatment any or every illness including ailments, diseases, infections by one method and by said compounds is not enabled by the instant disclosure.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,7, 24,26, 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter et al. (US 5,114,851).

In claim 1, applicant claims a compound comprising a given formula (I) “wherein: X₁A is a residue of a releasable biological active moiety.....” Porter et al. disclose applicant’s compound (formed between thrombin and the trans-isomer of O-hydroxyl- α -methylcinnamic acid) comprising said given formula (I) wherein: X₁A is a residue of a releasable biological active moiety (the enzyme, thrombin (labeled ENZ-O)) (see col. 1, line 45 to col. 2, line 12). It should be noted that for this compound, R₁= CH₃, R₂= R₃= R₄= R₅= R₆=Z = H, and Z=O. Porter et al. also disclose that the compound can undergo photoisomerization which leads to the (deacylation of the enzyme (i.e. is the release of the enzyme (the biologically active moiety)). In claim 2, applicant claims “the compound of claim 1, wherein X₁ is O, NH, or S.” Porter et al. disclose applicant’s compound of claim 2, wherein X₁ is O and R₁= CH₃, R₂= R₃= R₄= R₅= R₆=Z = H, and Z=O (see col. 1, line 45 to col. 2, line 12). Claim 3 is drawn to the compound of claim 2, wherein said residue of said biologically active moiety is selected from the group consisting of synthetic or naturally occurring organic compounds. Porter et al. disclose applicant’s compound of claim 3 wherein said biologically active moiety is a naturally occurring organic compound (the enzyme, thrombin). Claim 7 is drawn to the compound of claim 2, wherein said residue of

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said biologically active moiety is selected from the group consisting of proteins, polysaccharides Porter et al. disclose applicant's compound of claim 7 wherein said residue of said biologically active moiety is a protein (i.e. the enzyme thrombin). In claim 34, applicant claims "a method of preparing a conjugate, comprising: reacting a cinnamic acid derivative" of a given formula "wherein X₄ is a reactive terminal group with a biologically active moiety under conditions sufficient to cause covalent attachment of said biologically active moiety to said cinnamic acid derivative." Porter et al. disclose applicant's method of preparing a conjugate, comprising: reacting a cinnamic acid derivative (O-hydroxy- α -methylcinnamic acid) of said given formula containing an (OH) reactive terminal group, with a biologically active moiety (thrombin) to cause covalent attachment of said biologically active moiety to said cinnamic acid derivative (O-hydroxy- α -methylcinnamic acid) to give an acyl-enzyme (see col.1, line 45 to col. 2, line 12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (Guangdong Yixue (1997), 18 (5), 345) in view of Porter et al.

In claim 29, applicant claims a method of treatment comprising: administering to a mammal in need of such treatment an effective amount of a compound of claim 1, where X₁A is a residue of a biologically active moiety.

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Li et al. disclose a method of treatment Urinary bladder massive bleeding because of carcinoma and hemorrhagic cystitis comprising: administering to a mammal (patient) in need of such treatment an effective amount of a thrombin (see abstract).

Porter et al. disclose applicant's compound (formed between thrombin and the trans-isomer of O-hydroxyl- α -methylcinnamic acid) comprising said given formula (I) wherein: X_1A is a residue of a releasable biological active moiety (the enzyme, thrombin (labeled ENZ-O)) (see col. 1, line 45 to col. 2, line 12). It should be noted that for this compound, $R_1 = CH_3$, $R_2 = R_3 = R_4 = R_5 = R_6 = Z = H$, and $Z = O$. Porter et al. also disclose that the compound can undergo photoisomerization which leads to the (deacylation of the enzyme (i.e. is the release of the enzyme (the biologically active moiety) (see col. 1, line 45 to col. 2, line 12).

The difference between applicants' claimed method and the method of Li et al. is that Li et al. do not disclose the compound used for treatment.

However, Porter disclose that Li et al. compound (the enzyme, thrombin) can be released from Porter's compound (formed between thrombin and the trans-isomer of O-hydroxyl- α -methylcinnamic acid), via cleavage by photoactivation (see col. 1, line 45 to col. 2, line 12).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Li et al. in order to treat, and to use Porter et al. compound, since Porter et al. disclose that Li et al.'s compound can be released from Porter et al. compound via cleavage (via deacylation), based on availability and need.

One having ordinary skill in the art would have been motivated, to the process of Li et al. in order to treat, and to use Porter et al. compound, since Porter et al. disclose that Li et al.'s compound can be released from Porter et al. compound via cleavage (via deacylation), based on

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availability and need. Claims 30-33, which are drawn to the method of further exposing said compound to specific energy source and energy sources of specific wavelength, are also encompassed by this rejection, because it is obvious to use some source of photoactivation (like light) to cause the release of the biologically active moiety, since Porter et al. also disclose that their compound releases the biologically active moiety when photoactivated.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 5-23,25,27,28 to be unobvious over the prior art of record and may to be allowable over the prior art of record provided they are rewritten in a form independent of a rejected claim. The present invention relates to a compounds comprising a given formula (I) with a residue of a releasable biological active moiety. The invention also relates to method of preparing and using said compounds. The most relevant prior art documents (US 5,114,851) to this invention disclose compounds that are similar to those of the prior art.

However, though the compounds of the present invention are generally similar to those claimed in the prior art documents, some compounds possess differences (for example differences in chemical substituents) that are unobvious to those of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be

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reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

August 8, 2003.


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200